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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/077,312	02/15/2002	John McKenzie	271/094	3792

30452 7590 06/29/2004

EDWARDS LIFESCIENCES CORPORATION  
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EXAMINER

CHATTOPADHYAY, URMI

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/077,312

Applicant(s)

MCKENZIE ET AL.

Examiner

Urmi Chattopadhyay

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-10 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. The amendment filed 3/25/04 has been entered. Changes to the abstract, specification and Figure 5 have been approved by the examiner. Claims 4, 5 and 13-32 have been canceled. Claims 1-3 and 6-12 are pending, of which claim 11 is withdrawn from consideration. The claims being considered for further examination on the merits are 1-3, 6-10 and 12.

### ***Information Disclosure Statement***

2. The Katz et al. reference under "Non Patent Literature" in the Information Disclosure Statement filed 2/15/02 has been considered. This reference is cited and initialed on the enclosed PTO-892.

### ***Interference***

3. Claims 1-3 and 6-12 of this application have been copied from U.S. Patent No. 6,254,563 for the purpose of an interference.

4. Applicant has failed to meet the requirements for a request by applicant for interference with a patent, as set forth in 37 CFR 1.607(a)(2)-(a)(4). Specifically, applicant has failed to present a proposed count, identify at least one claim in the patent corresponding to the proposed count, and present at least one claim corresponding to the proposed count or identify at least one claim already pending in its application that corresponds to the proposed count.

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5. Applicant has applied each limitation or element of each of the copied claim(s) to the disclosure of the application. However, the cited line references to the current specification and priority application 08/854,806, now USPN 6,231,544, do not specifically disclose “a filter mesh material of varying porosity”, as required by claim 1. The ‘544 patent simply discloses the pore size as being within a certain preferred range. This can mean, for example, that all the pores are 130  $\mu\text{m}$ , which falls within the most preferred range of 120-150  $\mu\text{m}$ . It does not necessarily mean that the mesh material has varying porosity (pores of different sizes). Because there is not adequate support for this claimed limitation in the ‘544 patent, the current application does not receive benefit of the ‘544 filing date of 5/12/97. The current application has an effective filing date of the date it was filed, 2/15/02.

6. Because the effective filing date of the application is more than 3 months after the effective filing date of the patent (6,254,563), 37 CFR 1.608(b) requires that the applicant must file (1) evidence, such as patents, publications *and* other documents, *and* one or more affidavits or declarations which demonstrate that applicant is prima facie entitled to a judgment relative to the patentee, *and* (2) an explanation stating with particularity the basis upon which the applicant is prima facie entitled to the judgment. Applicant’s filing of a Declaration on 3/25/04, which simply lists the priority documents, is not sufficient to prove an effective filing date of 5/12/97.

7. Because applicant is claiming the same invention as a patent which has an earlier effective United States filing date and there is not a statutory bar against the application, and the applicant has not submitted the items required by 37 CFR 1.608(a) and (b), as appropriate, the application can be rejected under 35 U.S.C. 102(e)/103. The patent cannot be overcome by an affidavit or declaration under 37 CFR 1.131 but only through interference proceedings. Note,

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however, 35 U.S.C. 135(b) and MPEP § 2307.02. An affidavit under 37 CFR 1.608(b) or evidence and an explanation under 37 CFR 1.608(b), as appropriate, must be submitted and it should be stated, if applicable, that the patentee has been accorded the benefit of an earlier U.S. application.

### *Specification*

8. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

a) Claim 1: “filter mesh material of varying porosity” (see paragraph 5, *supra*)

b) Claim 2: “upstream sealing member comprises an inflatable toroidal balloon”; the current application does not disclose how the inflatable toroidal balloon of USPN 6,231,544 would be combined or modified with the embodiments of the current application.

c) Claim 3: “a perfusion lumen within said catheter shaft in fluid communication with a space exterior to said expandable conduit”; while USPN 6,231,544 does disclose a guide wire lumen, there is no disclosure of the lumen being configured to be used as a perfusion lumen.

d) Claim 6: “an occlusion member for selectively occluding said expandable conduit”; while USPN 6,231,544 does disclose an occlusion member, it is for occluding the vessel and not the expandable conduit. In fact, it is disclosed as *not* contacting the expandable conduit.

Therefore, the occlusion member of the ‘544 does not provide support for an occlusion member for selectively occluding said expandable conduit.

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e) Claim 7: “an infusion lumen within said catheter shaft having an infusion port upstream of said occlusion member” (dependent on claim 6)

f) Claim 8: “a second perfusion lumen within said catheter shaft” (dependent on claim 7); the cited figure and lines of USPN 6,231,544 do not disclose the second lumen.

g) Claim 10: “said occlusion member is an inflatable occlusion balloon” (dependent on claim 6)

9. The specification of neither the current application nor USPN 6,231,544 provides support for the above listed limitations. Because they were originally claimed at the time of filing, they can and must be included into the written specification. This application is considered a CIP of 09/642,570.

### ***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Independent claim 1 contains a limitation (“filter mesh material of varying porosity”) that was not previously disclosed as part of the invention. Therefore, claims 1-3 and 6-12 do not receive benefit of the earlier filing dates of the parent applications. The effective filing date of claims 1-3 and 6-12 is the date they were filed, 2/15/02.

12. Claims 1-3, 6-10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Macoviak et al. (USPN 6,139,517, as cited in applicant’s IDS).

Macoviak et al. discloses a catheter apparatus for use in a body with all the elements of claim 1. See columns 3-4, lines 53-32 and figures for a catheter shaft and an expandable conduit defined by a filter mesh material (column 17, lines 25-26) of varying porosity (column 17, lines 54-56) mounted on the catheter shaft. The expandable conduit has an upstream end and a downstream end (column 3, lines 53-55). The expandable conduit has a collapsed position in which the expandable conduit is collapsed toward the catheter shaft and an expanded position in which the upstream end of the expandable conduit is open to fluid flow (see figures). An upstream sealing member at the upstream end of the expandable conduit creates a seal between the upstream end of the expandable conduit and an internal wall of the body passage (columns 5-6, lines 66-3).

Claim 2, see column 4, lines 8-10 for inflatable toroidal balloon.

Claim 3, see column 7, lines 49-50 for a perfusion lumen (122).

Claims 6, 7 and 10, see claims 8, 9 and 29, of Macoviak et al., respectively.

Claim 8, see column 12, lines 28-29 for second perfusion lumen.

Claim 9, see column 9, lines 28-33 for tubular sheath (138).

Claim 12, see column 7, lines 26-27 for catheter shaft positioned internal to the expandable conduit.

### ***Response to Arguments***

13. Applicant's arguments filed 3/25/04 have been fully considered but they are not persuasive. Applicant argues that claims 1-10 are entitled to an effective filing date of 5/12/97, so the reference to Macoviak et al. (USPN 6,139,517) is not prior art. The examiner disagrees.

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As explained in paragraph 5, *supra*, there is no support for “a filter mesh material of varying porosity” in claim 1 in the current application or in priority document USPN 6,231,544.

Therefore, claim 1 and all claims dependent thereon, are not entitled to the filing date of the ‘544 patent. The effective filing date of the current application is 2/15/02. The Macoviak et al. reference (USPN 6,139,517) is indeed prior art and can rightfully be used to reject applicant’s claims under 35 U.S.C. § 102(b).

### ***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

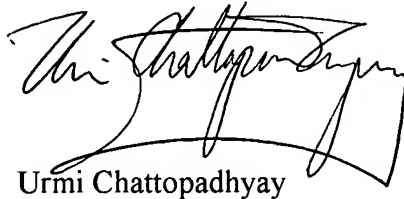
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



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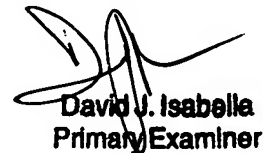
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 872-9306. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay

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David J. Isabella  
Primary Examiner